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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/937,864

12/20/2001

Thomas Ried

14014.0319U2

8947

7590

01/15/2003

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EXAMINER

YU, MISOOK

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 01/15/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,864

Applicant(s)

RIED ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 7-25 is/are pending in the application.
- 4a) Of the above claim(s) 21-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, and 7-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Newly submitted claims 21-25 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions. Newly submitted claims 21-25 are materially distinct methods which differ in objectives, method steps, response variables, and criteria for success. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-25 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

This application contains claims 21-25 drawn to a nonelected invention. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1, 2, and 7-25 are pending and claims 1, 2, and 7-20 are examined on merits.

Claim Rejections - 35 USC § 102

Claims 1, 2, 7-15, 17 and 19 **remain rejected** for the reasons set forth in the previous Office Action under 35 U.S.C. 102(b) as being anticipated by WO97/38313 (IDS A2).

Claims 1, 2, 7-15, 17 and 19 are interpreted as drawn to cancer detection method by enriching circulating epithelial cells by positive selection and detecting a hybridization pattern with a probe or multiple probes using various conventional detection methods.

Applicant argues the present invention are positive/selection processes with the enrichment by binding of the cancer cell rather than the non-rare blood cells and WO 97/38313 does not teach the instant invention. Applicant appears to argue that the main difference between the reference and the instant invention lies in the selection

process of the cancer cells from blood. Applicant argues that the instant invention utilizes positive selection process while the reference utilizes the negative selection process for the rare circulating cancer cells. These and other arguments have been fully considered but found unpersuasive because WO 97/38313 at Example 10 at page 35-37 teaches a method of enriching and screening for presence of a cancer cell from patients' blood by contacting the sample with an agent (i.e. anti-cytokeratin antibody) that binds to the epithelial cells as well as detecting cancer cells using various methods known in the art such as FISH. Further the reference teaches methods of separating and detecting cancer cells using immunomagnetic beads and other methods known in the art (see page 2) including the instantly claimed "positive selection", wherein a rare cell (i.e. circulating cancer cell) is bound to a binding agent such as antibody, thereby bound cancer cell is separated from the non-cancer cells (especially note page 2, lines 16-18). WO97/38313 further teaches detecting the hybridization pattern using various conventional detection methods (see page 21 to the first paragraph of page 26) and multiple probes (Example 7). The disclosed examples of probe associated with specific cancer and a genetic marker are PSMA, PSA, and centromeric regions of chromosomes 7, 8, 18 (page 21-22). Further, WO97/38313 teaches methods of determining status and progress of cancer patient, and monitoring efficacy of cancer treatment at page 3 lines 18-26, page 25, lines 19-26, examples 2, 7 and 11.

Thus, claims 1, 2, 7-15, 17 and 19 are anticipated by WO97/38313.

Claims 16, 18, and 20 **remain rejected** under 35 U.S.C. 102(a) as being anticipated by Racila et al (IDS A26).

Applicant states that the instant application discusses Racila et al and J. Uhr (one of the inventors in the instant application) is an author in Racila et al (IDS A26): This statement is correct. Applicant is reminded that Racila et al (IDS A26) is a publication by others even though one of the inventors is an author of the reference. Applicant argues that the instant claims 16, 18, and 20 are not anticipated ^{by} Racila et al because the complex formed in Racila et al was only used to indicate identification of epithelial cells, thus, the limitation "detection of the complex can distinguish a non-cancer cell from ~~c~~ cancer cell" is not met. However, this argument is not convincing

because Racila et al teach the complex formed in Racila et al (i.e., anti-cytokeratin and cytokeratin complex, and anti-mucin and mucin complex) is indicative of cancer cells.

Note abstract.

Thus, claims 16, 18, and 20 are anticipated by Racila et al.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

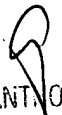
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Art Unit: 1642

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Misook Yu
December 26, 2002


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SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1300